



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,096	12/02/2003	David K. Swanson	015916-304	6001

21836 7590 03/07/2006

HENRICKS SLAVIN AND HOLMES LLP
SUITE 200
840 APOLLO STREET
EL SEGUNDO, CA 90245

EXAMINER

ROANE, AARON F

ART UNIT	PAPER NUMBER
----------	--------------

3739

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/727,096	Applicant(s) SWANSON, DAVID K.	
	Examiner Aaron Roane	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-12 and 28-46 is/are pending in the application.
- 4a) Of the above claim(s) 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-11 and 28-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/22/2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-11 and 28-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Independent claims 7, 28 and 43 recite a tissue stimulation element or means that is too small to form a transmural lesion in myocardial tissue. Although Applicant recites various dimensions of the tissue stimulation element or means and more importantly gives some examples of operating parameters (see for example claims 31-39 and pages 24-27 of the specification), the specific recitation in the independent claims does not explicitly set forth a threshold size. Additionally, it can be appreciated by one of ordinary skill in the art that creating a transmural lesion depends on several parameters, i.e., current, duration of application, etc. and that a particular sized tissue stimulation element or means maybe used in one modality to create transmural lesion while in another modality it may be used in a manner that does not create and is incapable of creating transmural lesions.

In order to provide an examination, the examiner interprets the recitation that the tissue stimulation element or means that is too small to form a transmural lesion in myocardial tissue as intended use.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 7-11, 28-30, 36 and 40-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Bertolero et al. (USPN 6,849,075 B2).

Regarding claims 7-11, 28, 36, 40, 41 and 43-46, Bertolero et al. disclose a surgical apparatus, comprising: a flexible tube (112 and analogous counterparts in other embodiments) defining a proximal region and a distal region, a suction device (402 also see analogous counterparts in other embodiments) associated with the distal region of the tube and coupled to a suction source (120 or analogous counterparts in other embodiments); and a tissue stimulation element in the form of an electrode (410)

Art Unit: 3739

operatively connected to a source of stimulation energy (122 or analogous counterparts in other embodiments), see col. 9 through col. 17, line 6 and figures 1-6. Bertolero et al. also disclose a flexible suction device that has a cup shaped opening (412), see col. 16.

Regarding claims 29 and 30, Bertolero et al. disclose the claimed invention, see figures 2-5.

Regarding claim 42, Bertolero et al. further disclose the suction device comprises a substantially cup-shaped device having a bottom surface that defines the outer perimeter of the cup-shaped device and the tissue stimulation element is located on the bottom surface, see figure 2-4a.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31-39 rejected under 35 U.S.C. 103(a) as being unpatentable over Bertolero et al. (USPN 6,849,075 B2).

Regarding claims 31-33 and 37-39, Bertolero et al. discloses the claimed invention except for explicitly reciting the various recited tissue stimulation element dimensions.

However, it would have been an obvious matter of design choice to a tissue stimulation element having a perimeter of about 1.5 to 3.0 mm, a thickness of about 0.01mm and/or a diameter of about 0.5 to 1.0 mm, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Regarding claims 34 and 35, Bertolero et al. discloses the claimed invention except for explicitly reciting the source of stimulation energy is configured to supply stimulation pulses that are about 1 millisecond in duration and about 10 mA in amplitude and/or the source of stimulation energy is configured to supply two stimulation pulses per second. These recitations are interpreted as intended uses, a recitation of the intended use(s) of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Additionally, the examiner takes official notice and states that it is well known in the art to provide electrosurgical devices with power supplies that are programmable, automated or capable of activating and deactivating the energy quickly and repetitively.

Response to Arguments

Applicant's arguments with respect to claims 7-11 and 28-46 have been considered but are moot in view of the new ground(s) of rejection. In addition to newly provided prior art (in Bertolero et al., a 112 enablement rejection has been made.

This action is FINAL.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 3739

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 7AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.R. *A.R.*
March 2, 2006

Roy D. Gibson
ROY D. GIBSON
PRIMARY EXAMINER